

INSTRUCTIONS FOR PROGRAM MANAGERS

Don't forget to delete this Instruction Section from your final Order!

This Boilerplate Order contains Instructional Notes to Program Managers throughout the text. The notes are in red and bold type in the text to make them easy to find. When the Order is completed make certain that all of these notes have been deleted. To ensure that all notes are deleted, use "Edit, Find and Replace" perform a global search for [**Note to Program Managers**].

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:

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Premanufacture Notice Number:

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Consent Order for Contract Manufacturer

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. _____ (“the Contract Manufacturer”) has entered into a contract with _____ (“the Company”) to manufacture or import exclusively for the Company the chemical substance: _____ (P- ____ - ____)(“the PMN substance”). The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in the United States by the Contract Manufacturer, except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements

of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Contract Manufacturer begins commercial manufacture of the PMN substance for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Contract Manufacturer begins to manufacture the PMN substance for use in the United States, no further activity by the Contract Manufacturer involving the PMN substance is exempt as “solely for export” even if some amount of the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development (R&D). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36.

(3) Byproducts. The requirements of this Order do not apply to the PMN substance when it is produced, without separate commercial intent, only as a “byproduct” as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when it is manufactured, pursuant to any of the exemptions in 40 CFR

720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(c) Automatic Sunset. If the Contract Manufacturer has obtained for the PMN substance a Test Market Exemption (TME) under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption (LVE) or Low Release and Exposure Exemption (LoREX) under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, IMPORT, PROCESSING,
DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL
PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

As a condition of manufacturing or importing the PMN substance for the Company, the Contract Manufacturer is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the PMN substance for any non-exempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the environmental effects **[Note to Program Managers: Edit as appropriate.]** of the substance, and the completion of EPA's review of, and regulatory action based on that information, except in accordance with the conditions described in this Order.

TESTING

Triggered Testing Requirements. The Contract Manufacturer is prohibited from manufacturing or importing the PMN substance beyond the following aggregate manufacture and import volumes ("the production limits"), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in the Testing section of the Consent Order for the Company.

Production Limit

Study

Guideline

HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Contract Manufacturer shall develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Contract Manufacturer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Contract Manufacturer may rely on an existing hazard communication program, including an existing program established under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written

program shall include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a TSCA section 5(e) consent order signed by the Contract Manufacturer or to a TSCA section 5(a)(2) SNUR at 40 C.F.R. Part 721, subpart E. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Contract Manufacturer is required either by another Order issued under section 5(e) of TSCA, or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Contract Manufacturer will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Contract Manufacturer will use to inform contractors of the presence of the PMN substance in the Contract Manufacturer's workplace and of the provisions of this Order if employees of the contractor work in the Contract Manufacturer's workplace and are reasonably likely to be exposed to the PMN substance while in the Contract Manufacturer's workplace.

(b) Labeling.

(1) The Contract Manufacturer shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(I) A statement of the health hazards(s) and precautionary measure(s), if any, identified in paragraph (f) of this section or by the Contract Manufacturer, for the PMN substance.

(II) The identity by which the PMN substance may be commonly recognized.

(III) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified in paragraph (f) of this section, or by the Contract Manufacturer, for the PMN substance.

(IV) A statement of exposure and precautionary measure(s), if any, identified in paragraph (f) of this section, or by the Contract Manufacturer, for the PMN substance.

(ii) The Contract Manufacturer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Contract Manufacturer need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Contract Manufacturer shall not remove or deface an existing label on

containers of the PMN substance obtained from persons outside the Contract Manufacturer unless the container is immediately re-labeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Contract Manufacturer shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(I) The information prescribed in subparagraph (b)(1)(i) of this section.

(II) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed. (4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Contract Manufacturer, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29

CFR 1900.1200), the Contract Manufacturer may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Contract Manufacturer determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Contract Manufacturer must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(6) If the Contract Manufacturer becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the label within 3 months from the time the Contract Manufacturer becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Contract Manufacturer's workplace, the Contract Manufacturer must add the new information to the label before the PMN substance is reintroduced into the workplace.

(c) Material Safety Data Sheets.

(1) The Contract Manufacturer must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common name are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the Contract Manufacturer, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Contract Manufacturer, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (f) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Contract Manufacturer.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures. The MSDS must identify any New Chemical Exposure Limits specified in paragraph (b) of the New Chemical Exposure Limit section of this Order and must contain the information specified in the graduated respirator table in paragraph (e)(2) of the New Chemical Exposure Limit section.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Contract Manufacturer, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Contract Manufacturer, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Contract Manufacturer.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Contract Manufacturer or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Contract Manufacturer must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Contract Manufacturer may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Contract Manufacturer becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Contract Manufacturer becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Contract Manufacturer's workplace, the Contract Manufacturer must add the new information to the MSDS before the PMN substance is reintroduced into the workplace.

(6) The Contract Manufacturer must ensure that persons receiving the PMN substance from the Contract Manufacturer are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Contract Manufacturer may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Contract Manufacturer must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Contract Manufacturer must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as exposure monitoring conducted by the Contract Manufacturer, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the PMN substance as specified in paragraph (f) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including specific procedures the Contract Manufacturer has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Contract Manufacturer under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) Existing Hazard Communication Program. The Contract Manufacturer need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(f) Environmental Hazard and Precautionary Statements. The following environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the

MSDS as specified in paragraph (c) of this section:

- (1) Environmental hazard statements. This substance may be:
 - (i) toxic to fish.
 - (ii) toxic to aquatic organisms.
- (2) Environmental hazard precautionary statements. Notice to users:
 - (i) disposal restrictions apply.
 - (ii) spill clean-up restrictions apply.
 - (iii) do not release to water.
- (3) The human and environmental hazard and precautionary statement on the label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

MANUFACTURING

(a)(1) Prohibition. The Contract Manufacturer shall not begin manufacture or import of the PMN substance until the Contract Manufacturer or the Company receives a fully executed copy of the Consent Order for Contract Manufacture from EPA.

(2) The Contract Manufacturer shall not cause, encourage, or suggest the manufacture or import of the PMN substance by any other person.

(3) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Contract Manufacturer is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Contract Manufacturer is

so notified, subparagraph (a)(1) shall not expire until EPA notifies the Contract Manufacturer in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(4) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Contract Manufacturer shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR.

(b) The Contract Manufacturer shall not manufacture the PMN substance:

- (1) In non-enclosed processes;
- (2) In the United States;
- (3) Beyond an aggregate manufacture and importation volume of _____;
- (4) Beyond an annual manufacture and importation volume of _____;
- (5) In the form of a powder;
- (6) In the form of a solid;
- (7) In the form of a liquid;
- (8) In the form of a gas; or
- (9) Other: _____.

PROCESSING

(a) The Contract Manufacturer shall not process the PMN substance:

- (1) In non-enclosed processes;
- (2) Beyond the site of manufacture or import;

- (3) In the form of a powder;
- (4) In the form of a solid;
- (5) In the form of a liquid;
- (6) In the form of a gas; or
- (7) Other:_____.

USE

(a) The Contract Manufacturer shall not use the PMN substance:

- (1) In non-enclosed processes;
- (2) Beyond the site of manufacture or import;
- (3) Other than as an intermediate;
- (4) Other than as a site-limited intermediate;
- (5) As an intermediate where the concentration of the PMN substance in the product intended for distribution in commerce exceeds ____ percent;
- (6) Other than as described in the PMN;
- (7) For non-industrial applications;
- (8) For commercial applications;
- (9) For non-commercial applications;
- (10) In consumer products;
- (11) In the form of a powder;
- (12) In the form of a solid;
- (13) In the form of a liquid;
- (14) In the form of a gas;

- (15) Involving an application method that generates a vapor, mist, or aerosol;
- (16) Involving an application method that generates a dust; or
- (17) Other: _____.

DISTRIBUTION

(a) Distribution Requirements. Except after the PMN has been completely reacted (or _____) **[Note to Program Managers: If applicable to the specific PMN substance, identify a state or states in which exposure to the PMN substance no longer presents a significant risk, e.g., “incorporated into a polymer matrix”, “adhered onto film”, or similar.]** or as provided in paragraph (b), the Contract Manufacturer shall distribute the PMN substance outside the Contract Manufacturer, including for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Not further distribute the PMN substance to any other person, including for disposal, until after the PMN substance has been completely reacted (cured) or _____. **[Note to Program Managers: If applicable to the specific PMN substance, identify a state or states in which exposure to the PMN substance no longer presents a significant risk, e.g., “incorporated into a polymer matrix”, “adhered onto film”, or similar.]**

(2) Comply with the same requirements and restrictions, if any, required of the Contract Manufacturer in the Protection in the Workplace and the New Chemical Exposure Limit sections of this Order, or _____.

(3) Comply with the same requirements and restrictions, if any, required of the Contract Manufacturer in the Hazard Communication Program section of this Order, or _____.

(4) Comply with the same environmental release restrictions, if any, required of the

Contract Manufacturer in the Disposal and Release to Water sections of this Order, or _____.

(5) Not process the PMN substance:

- (i) In non-enclosed processes;
- (ii) At a site not in that person's control;
- (iii) Except as described in the PMN;
- (iv) In the form of a powder;
- (v) In the form of a solid;
- (vi) In the form of a liquid;
- (vii) In the form of a gas; or
- (viii) Other:_____.

(6) Not use the PMN substance:

- (i) At a site not under the person's control;
- (ii) In non-enclosed processes;
- (iii) Other than as an intermediate;
- (iv) Other than as a site-limited intermediate; or
- (v) As an intermediate where the concentration of the PMN substance in the

product intended for distribution in commerce exceeds ____ percent;

- (vi) Other than as described in the PMN;
- (vii) For non-industrial applications;
- (viii) For commercial use;
- (ix) For non-commercial use;
- (x) In consumer products;
- (xi) In the form of a powder;

- (xii) In the form of a solid;
- (xiii) In the form of a liquid;
- (xiv) In the form of a gas;
- (xv) Involving an application method that generates a vapor, mist, or aerosol;
- (xvi) Involving an application method that generates a dust; or
- (xvii) Other: _____.

(b) Temporary Transport and Storage. Notwithstanding paragraph (a), the Contract Manufacturer may distribute the PMN substance outside the Contract Manufacturer for temporary transport and storage in sealed containers (labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Order) provided the following two conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substance may be distributed only to the Company or a person who has given the Contract Manufacturer the written agreement required by paragraph (a).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substance may occur only while the PMN substance is in the possession and control of the Contract Manufacturer or a person who has given the Contract Manufacturer the written agreement required by paragraph (a).

(c) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Contract Manufacturer obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section or, after paragraph (a)(1) expires in accordance with subparagraph (d)(1), has engaged in a

significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Contract Manufacturer shall cease supplying the substance to that recipient, unless the Contract Manufacturer is able to document each of the following:

(1) That the Contract Manufacturer has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Contract Manufacturer received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (a) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substance and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (c)(2) of this Distribution section, the Contract Manufacturer obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Contract Manufacturer shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(d) Sunset Following SNUR. (1) Paragraph (a)(1) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA,

unless the Contract Manufacturer is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Contract Manufacturer is so notified, paragraph (a)(1) of this Distribution section shall not expire until EPA notifies the Contract Manufacturer in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substance and paragraph (a)(1) of this Distribution section expires in accordance with subparagraph (d)(1), the Contract Manufacturer shall notify each person to whom it distributes the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations. After promulgation of a SNUR and expiration of subparagraph (a)(1), such notice may substitute for the written agreement required in the introductory clause of paragraph (a); so that, if the Contract Manufacturer provides such notice to the persons to whom it distributes the PMN substance, then the Contract Manufacturer is not required to obtain from such persons the written agreement specified in paragraph (a).

DISPOSAL

(a)The Contract Manufacturer shall dispose of the PMN substance and any waste stream containing the PMN substance only as follows. This provision does not supersede or preempt any applicable federal, state, and local laws and regulations if those laws are more stringent than the requirements below.

- (1) The PMN substance must be disposed of only by:
 - (i) incineration;
 - (ii) landfill;
 - (iii) deep well injection;
 - (iv) other: _____
- (2) Waste streams from manufacture must be disposed of only by:
 - (i) incineration;
 - (ii) landfill;
 - (iii) deep well injection;
 - (iv) other: _____
- (3) Waste streams from processing must be disposed of only by:
 - (i) incineration;
 - (ii) landfill;
 - (iii) deep well injection;
 - (iv) other: _____
- (4) Waste streams from use must be disposed of only by:
 - (i) incineration;
 - (ii) landfill;
 - (iii) deep well injection;
 - (iv) other: _____
- (5) The Contract Manufacturer shall not dispose of or release the PMN substance into the environment.

RELEASE TO WATER

(a) This provision does not supersede or preempt any applicable federal, state, and local laws and regulations. (Those other laws may be more stringent than the requirements below.) The Contract Manufacturer is prohibited from any predictable or purposeful release of the PMN substance, or any waste stream from _____ (manufacturing/processing/use) containing the PMN substance:

(1) Into the waters of the United States;

(2) Into the waters of the United States without application of one or more of the following specified treatment technologies either by the discharger or, in the case of a release through publicly-owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

- (i) Chemical precipitation and settling;
- (ii) Biological treatment (activated sludge or equivalent) plus clarification;
- (iii) Stream stripping;
- (iv) Resin or activated carbon adsorption;
- (v) Chemical destruction or conversion;

(vi) Primary wastewater treatment;

(3) Into the waters of the United States without primary wastewater treatment, and secondary wastewater treatment as defined in 40 CFR Part 133.

(4)(i) Into the waters of the United States if the quotient from the formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = N \text{ parts per billion}$$

exceeds _____, when calculated using the methods described in 40 CFR 721.91. However, 40

CFR 721.91(a)(4) does not apply. Instead, if the waste stream containing the PMN substance will be treated using _____, then the amount of PMN substance reasonably likely to be removed from the waste stream by such treatment may be subtracted in calculating the number of kilograms released. No more than ___ percent removal efficiency may be attributed to such treatment. **[Note to Program Managers: Use this language, starting from “However, 40 CFR 721.91(a)(4) does not...” only when EPA has received and reviewed removal rate data..]**

(ii) In lieu of calculating the quotient in subparagraph (4)(i), monitoring or alternative calculations may be used to predict the surface water concentration expected to result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on a written request to approve monitoring procedures or alternative calculations within 90 days after such a request is received. The Agency will inform the Contract Manufacturer of the disposition of such requests in writing and, where a request is denied, will explain the reasons therefor.

III. RECORDKEEPING

(a) Records. The Contract Manufacturer shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Contract Manufacturer. Any amounts or batches of the PMN substance eligible for the Export exemption in Section I, Paragraph (b)(3) of this Order, are

exempt from all the requirements in this Recordkeeping section, if the Contract Manufacturer maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the Research and Development exemption in Section I, Paragraph (b)(4) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Contract Manufacturer maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Contract Manufacturer shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import;

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Contract Manufacturer directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the address, of all sites of manufacture, import, processing, and use;

(5) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(6) Copies of labels required under the Hazard Communication Program section of this Order;

(7) Copies of material safety data sheets required by the Hazard Communication Program section of this Order;

(8) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Processing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(9) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of PMN substance disposed. Where the estimated disposal volume is not known to the Contract Manufacturer and is not reasonably ascertainable by the Contract Manufacturer, the Contract Manufacturer must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements;

(10) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order;

(11) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and

(12) The Contract Manufacturer shall keep a copy of this Order at each of its sites where the PMN substance is manufactured or imported.

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Contract Manufacturer and its Contract Manufacturer, if applicable, and not to activities of

the Contract Manufacturer's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Contract Manufacturer is not required to respond to this “collection of information” unless this Order displays a currently valid control number from the Office of Management and Budget (OMB), and EPA so informs the Contract Manufacturer. The “collection of information” required in this TSCA §5(e) Consent Orders has been approved under currently valid **OMB Control Number 2070-0012**.

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA’s Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Contract Manufacturer facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Contract Manufacturer in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request may include, but are not limited to, the following:

(i) Expected dates and times when the PMN substance will be in production within the subsequent 12 months;

(ii) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(iii) Current job titles or categories for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(iv) Existing exposure monitoring data for workers who are involved in activities

associated with the PMN substance and may reasonably be exposed to the PMN substance;

(v) Records required by the Recordkeeping section of this Order; and/or

(vi) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Contract Manufacturer's Response. The Contract Manufacturer shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Contract Manufacturer's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Contract Manufacturer at the time of the request, the Contract Manufacturer's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information (CBI) that the Contract Manufacturer submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Contract Manufacturer may petition EPA at any time, based upon new information on the environmental effects or environmental release of the PMN substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the

Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Contract Manufacturer may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VI. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Contract Manufacturer waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Contract Manufacturer as to, the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Contract Manufacturer may have under TSCA.

Date

Wardner G. Penberthey, Acting Director
Chemical Control Division
Office of Pollution Prevention and Toxics

Date

Name:

Title:

Contract Manufacturer:

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labelled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

